Practice guidelines

Patient selection criteria for at-home cancer chemotherapy - formal consensus -

September 2003

Synopsis

Title	Patient selection criteria for at-home cancer chemotherapy
Publication date	September 2003
Type of document	Practice guidelines
Intended for	All those who may be involved in at-home chemotherapy: drug prescribers (oncologists or specialists), nurses, social workers, psychologists, GPs, pharmacists, coordinating staff
Requested by	Hospital and Organisation of Care Directorate (*DHOS*)
Produced by	ANAES – French National Agency for Accreditation and Evaluation in Healthcare (Guidelines Department)
Objectives	To establish consensus guidelines for selecting patients for at-home chemotherapy and for ensuring that this chemotherapy is administered to standards that are as safe as those of conventional hospitalisation and of a similar quality
Assessment method	Formal consensus method derived from the nominal group technique adapted by RAND/UCLA
Literature search	Unlimited period 105 references selected among 351 analysed
Project management	Project leader: Dr. Frédéric de Bels (Department head: Dr. Patrice Dosquet) Literature search: Frédérique Pagès assisted by Maud Lefèvre (Department head: Rabia Bazi) Secretarial work: Catherine Solomon-Alexander
Collaborations and participants	Learned societies Working group (Chair: Professor Jacques Bonneterre, medical oncologist, Lille) (included a preparatory group and an expert panel) Peer reviewers (For participants, see Annex 1)
Internal validation	ANAES Scientific Council (Referees: Professor Paul Landais, Professor Alain Vernenègre) Validated on 09/18/2003
Related documents	Full report (in French) Available on ANAES website (www.anaes.fr)
ANAES publications on related topics	*"Méthode d'élaboration d'une démarche de soins type à domicile pour une population définie de personnes en situation de dépendance"* (May 2004)

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Summary of the guidelines

Patient eligibility criteria for at-home cancer chemotherapy

The aim was to establish consensus guidelines for selecting patients able to receive cancer chemotherapy at home, and for ensuring that this chemotherapy is administered to standards that are as safe as those of conventional hospitalisation and of a similar quality.

Because there is little high-quality scientific evidence, the guidelines were produced by a formal expert consensus method. They are proposals giving the minimum requirements for the implementation, follow-up and analysis of procedures for at-home treatment.

The working group considered in turn:

(i) Criteria relating to the types of drugs and protocols that can be used for at-home chemotherapy (Box 1) and guidelines relating to drug toxicity (Box 2);

(ii) Treatment plan requirements for at-home chemotherapy (Box 3);

(iii) Criteria prompting reappraisal of at-home treatment during chemotherapy and post-chemotherapy monitoring (Box 4).

Box 1. Criteria regarding drugs and protocol for at-home chemotherapy

- The anticancer drug should be:
  - either included in the *rétrocession* list
  - or supplied by community pharmacists.
- In the case of parenteral administration (except SC):
  - The patient should agree to a long-term central venous access device.
  - The drug should:
    - either be in ready-to-use form
    - or be prepared in a central preparation unit in hospital
    - or, failing this, be prepared by the home care nurse (case by case basis).
- The protocol should be taken from the protocol manual of the hospital where the prescriber works.
- The nurse should be qualified to administer drugs at home.

Box 2. Guidelines relating to drug toxicity

- The prescribing doctor should check the drug marketing authorisations to identify any risk factors. They should assess the risks inherent to the medical environment (e.g. emergency procedures) and inform the patient of these risks before deciding, together with the cancer unit (UCPO), whether to allow at-home chemotherapy.
- The first cycle of parenteral (except SC) cancer chemotherapy should be given in the prescriber's hospital.
- The working group had reservations about at-home administration of the following drugs because of the risk of short-term toxicity and/or the lack of data: ifosfamide and cyclophosphamide given intravenously (IV) at very high doses, particularly in patients who have received anthracyclines; irinotecan; paclitaxel; oxaliplatin; etoposide (IV); alemtuzumab (IV). The first cycle of these drugs, and of rituximab and trastuzumab, should **always** be given in the prescribing doctor's hospital.
- Provided no immediate serious side-effects are anticipated, any cancer chemotherapy that is given or can be given during part-time hospitalisation may be offered to the patient at home.
- The intensive hydration and vigorous diuresis protocols required by high-dose methotrexate, cisplatin, ifosfamide and cyclophosphamide (IV) treatment are complex and should not be carried out in the home, except on a case-by-case basis.

Box 3. Treatment plan requirements for at-home chemotherapy

- A written treatment plan has been produced.
- The patient prefers at-home care and has consented to it.
- The patient has learnt to cope with their disease and has no severe psychological disorder.
- Patient and caregivers have acquired the minimum skills needed to carry out treatment safely.
- The following have agreed to participate in care:
  - the patient's GP or, failing this, another GP
  - an HAH structure, care network or independent nurse
  - all individuals needed to provide thorough and safe care (pharmacist, social worker, psychologist, etc.).
- The home is safe for the patient, the patient's family and for caregivers.
- Safe access to care and effective warning and emergency procedures are available.
- Family members and caregivers should agree to the patient's treatment plan. They should not be vulnerable or oppose at-home chemotherapy.
- The following factors do not exclude or restrict at-home chemotherapy: seriousness, severity or rate of progression of the disease, tumour type (solid tumour or malignant blood disorder), malnutrition or dehydration.

Box 4. Criteria prompting reappraisal of at-home chemotherapy

- No go-ahead from the GP, particularly if there are signs of severity or a need to admit the patient to hospital.
- Onset of complications due to administration route (i.e. signs of severity, diagnosis and treatment not possible); a specialist opinion has been sought.
- Onset of anaemia, thrombocytopenia or febrile neutropenia, or signs and symptoms suggestive of these complications (i.e. signs of severity, diagnosis and treatment not possible); a specialist opinion has been sought.
- Change in the selection criteria of the treatment plan (in particular, change to a type of chemotherapy that cannot be given at home, end of chemotherapy, patient's request, poor psychosocial environment, temporary interruption of treatment, refusal by GP or nurse to continue with care);
- Problems for the care team in providing care and maintaining a safe environment (particularly around the clock care, an effective warning and emergency procedure, and effective transmission and circulation of information).

The treatment plan should specify the procedures for readmitting the patient to hospital in an emergency and for flexibility in handling changes in care.

The working group emphasised that each selection criterion should not be considered in isolation but in relation to all the therapeutic, medical, psychological, social, environmental and administrative criteria making up a treatment plan compatible with the patient's wishes. How a doctor takes each of these criteria into account when deciding whether or not to offer at-home chemotherapy will vary with each individual.

I. Introduction

I.1 Objective

The aim was to establish consensus guidelines for identifying patients eligible for cancer chemotherapy at home, and for ensuring that this chemotherapy is administered to standards that are as safe as those of conventional hospitalisation and of a similar quality. The guidelines were produced at the request of the French Hospital and Organisation of Care Directorate (DHOS).

I.2 Scope of the guidelines

These guidelines cover cancer chemotherapy given under the Hospital at Home (HAH) system, by cancer care networks or by independent non-hospital practitioners.

They do not cover:
- part-time hospitalisation
- management of palliative care or pain (dealt with elsewhere)
- cancer chemotherapy in children.

II. Assessment method

The working group established criteria for selecting patients for cancer chemotherapy at home by considering:
(iv) types of chemotherapy that can be given at home to standards that are as safe as those of conventional hospitalisation and of a similar quality;
(v) patient assessment within a treatment plan (patients' and caregivers' preferences; medical, psychological, social and environmental criteria);
(vi) practical arrangements for administering chemotherapy at home and for post-chemotherapy monitoring.

Because there is little high-quality scientific evidence, some guidelines - particularly those concerning organisational matters - are only proposals addressing the minimum requirements for the implementation, follow-up and analysis of procedures for at-home treatment.

The basis for all the guidelines was agreement among professionals using a formal consensus method derived from the nominal group technique adapted by RAND/UCLA. The method is given in Annex 2.

III. Criteria governing types of cancer chemotherapy that can be given at home

III.1 Legislative framework

Anticancer drugs for at-home chemotherapy may be available on unrestricted prescription or, if they are subject to restricted prescription, should be

- either included in the French Minister of Health's *rétrocession* list
- or supplied by community pharmacists.

If they are licensed for hospital prescription or for initial hospital prescription only, the home treatment protocol should be taken from the treatment protocol manual ("*référentiel de traitement*") of the prescribing doctor's hospital. If not, it should be the subject of a clinical trial or an assessment procedure (covered by the Huriet law).

In addition, protocols should give preference to chemotherapy regimens that have been standardised at regional level (particularly within a single network) and, if possible, at national level and validated by published data.

III.2 Handling of anticancer drugs

- ***Oral drugs***

Anticancer drugs available in oral form can generally be regarded as safe. They should be used in preference to parenteral forms if both forms are equally effective. Packs suitable for non-hospital use would be useful. Safe handling does not remove the need for following the rules for prescription and information to ensure compliance with treatment, nor for specific post-chemotherapy monitoring as outlined in the initial treatment plan.

The patient should nevertheless be clearly told that at-home chemotherapy with an oral drug does not imply that their disease is any less serious or that the drug prescribed is less harmful than protocols for parental administration. Such misapprehensions could lead to poor compliance and reduced vigilance.

- ***Parenteral forms***

- Simple protocols and safe administration procedures

A central venous access device (CVAD) (whether or not totally implantable) is a prerequisite for intravenous cancer chemotherapy at home. Luer-lock connections on the infusion line are recommended. Caregivers must follow rigorous asepsis and maintenance procedures to avoid complications, particularly bleeding, infection and thromboembolism.

If the patient refuses CVAD implantation or if such a device is contraindicated, part-time hospitalisation is the best option. The refusal or contraindication should be noted in the patient's medical record.

A criterion for considering at-home cancer chemotherapy is the availability of drugs in ready-to-use forms. These are recommended. The development of these drugs at an acceptable cost should be encouraged despite the need to adjust the dose to body surface area.

Treatment regimens requiring complex monitoring are not recommended for home use because of the increased risk of error and toxicity.

- Administration at home by a qualified nurse

The hospital care team should ensure, directly or via the care network or HAH coordinator, that the nurse allocated to home care is qualified to give cancer chemotherapy at home and that a contract or agreement has been signed for waste disposal.

If necessary, the nurse's ability to handle anticancer drugs and maintain a central venous access, particularly a totally implantable device, can be developed, for example during the first cycle of chemotherapy in hospital. What constitutes good practice in relation to at-home chemotherapy should be set out in a "cancer chemotherapy procedures and information file" produced by the hospital and given to the nurse with each protocol.

- Safe preparation

Safe conditions for at-home chemotherapy are not necessarily available in every patient's home. In addition, the carer and the patient's household may be exposed to a risk of toxicity which cannot be accurately estimated for lack of data. The working group:

- recommended that drugs should be reconstituted and prepared in centralised preparation units within hospitals;
- encouraged the development of alternatives such as custom preparation by private laboratories, private service providers, or specialist pharmacies. This would, however, require quality and safety standards (relating to preparation, transport and traceability of drugs) and changes in current legislation;
- recommended that the possibility of preparing cancer chemotherapy drugs in the home should be examined on a case-by-case basis, particularly for protocols requiring preparation just before use. Here again, quality and safety standards are needed.

In all cases, a quality assurance procedure should be introduced to ensure product traceability and the safe management and disposal of waste. When the drugs are not prepared in the home, this procedure should cover:

- safe transport;
- administration within the period when the drug is stable after reconstitution;
- hygiene during transport and administration to minimise risk of infection.

These procedures should be validated by the Drugs and Sterile Medical Devices Committee (COMEDIMS) and the Nosocomial Infection Prevention Committee (CLIN) covering the prescribing doctor's hospital.

- ***Adverse events***

To date, no published data on serious adverse events have indicated any similarities or differences in survival and safety between chemotherapy at home and in hospital.

The working group recommended that the first cycle of parenteral treatment should be given in hospital to assess short-term tolerance (although immediate hypersensitivity reactions may also occur at a later date). It also gives the patient and the home care nurse an opportunity to observe the drug administration procedures.

- ***Patient eligibility criteria: Immediate hypersensitivity or anaphylactoid reactions and acute toxicity***

The working group could not advise on specific types of cancer chemotherapy that may be given in a domestic setting because they have a low risk of acute toxicity . Because there is no precise estimate of this risk in the literature and no access to data in marketing authorisation (AMM) dossiers, risks at home and in hospital cannot be estimated and compared. Risk also depends on the patient's risk factors (including distance from the hospital) and on the arrangements and emergency procedures specific to each structure or treatment method. Moreover, risks need to be considered in the context of drug categories judged to be acceptable in non-hospital settings.

The doctor prescribing chemotherapy should look for any risk factors, assess the risks within the medical environment, and inform the patient of these risks, before deciding, together with the UCPO[1], whether to allow at-home chemotherapy. This involves checking the adverse events, warnings and precautions given in the marketing authorisations. Working group members had reservations about home administration of the following drugs on the basis of the French marketing authorisations and their own experience:

- ifosfamide and cyclophosphamide given intravenously (IV) at very high doses, particularly in patients who have received anthracyclines
- irinotecan
- paclitaxel
- oxaliplatin
- etoposide (IV)
- alemtuzumab (IV).

For these drugs, and for rituximab and trastuzumab, they recommended that the first cycle should always be given in the prescribing doctor's hospital.

Many protocols require precautionary measures or special monitoring to avoid onset of adverse events, particularly immediate hypersensitivity reactions. These precautions should be complied with. Examples are administration of antiallergic premedication, bleomycin, and anti-microtubule agents such as docetaxel and paclitaxel (list not exhaustive) and use of 5-FU in patients with a history of coronary disease.

For safe at-home chemotherapy, two measures were strongly recommended:

(i) an appropriate and regularly checked emergency kit permanently available at the patient's home; this kit could be supplied on an advance prescription in the name of the patient;

(ii) a validated emergency procedure that includes the GP, the home care nurse and the emergency services centre (*centre 15*) and/or the prescribing doctor's own hospital department.

- ***Patient eligibility criteria: Medium-term toxicity and post-chemotherapy monitoring***

Medium- and long-term side effects will be the same whether treatment is given in the home or during part-time hospitalisation. The post-chemotherapy monitoring procedures will be similar. The working group felt that, despite the lack of data on the equivalent safety of both forms of treatment, any cancer chemotherapy that is or can be given during part-time

[1] Unités de Concertation Pluridisciplinaires en Oncologie: These are units within which health professionals from different disciplines examine patients' records together.

hospitalisation may also be offered in the home, provided no immediate serious side-effects are expected.

Some protocols call for compliance with special precautions to avoid side-effects. The working group considered that anticipated renal failure during high-dose methotrexate treatment or during cisplatin treatment or bladder toxicity during ifosfamide or cyclophosphamide (IV) treatment are reasons not to allow at-home chemotherapy as the protocols for intensive hydration and vigorous diuresis are complex. These protocols should therefore not be carried out in the home but may be considered on a case-by-case basis.

IV. Patient assessment within a treatment plan

Each patient should have a written treatment plan ("*projet thérapeutique*[2]*")* which covers medical, social, psychological and environmental factors as well as the patient's needs. Producing this plan and a multidisciplinary/professional patient assessment help to determine the methods used to care for the patient. The patient's GP, the allocated nurse, the network or HAH structure coordinator and the patient's usual local pharmacist should be involved as early as possible.

IV.1 Patients' and caregivers' preferences, information provision, psychological issues and education

- ***Patients' preferences and information provision***

Patient preference is the foremost criterion for eligibility for at-home chemotherapy. This is true whether at-home chemotherapy was suggested by the prescribing doctor or by the patient, and assumes that the protocol allows it. Moreover, the patient might prefer not only care at home, but care within the HAH system or a network, or care by an independent practitioner. The care team should be attentive to the patient's wishes. The patient should have received appropriate information that they can understand before making an informed decision, and they should be told that they can change their mind freely, at any time, when the treatment plan is produced or once at-home chemotherapy has started.

In the event of at-home chemotherapy, the hospital care team should complete the information they gave at the time of diagnosis with information about at-home chemotherapy:
- the pros and cons of home care compared with hospital care (whether full- or part-time);
- the procedures involved in home care, particularly constraints on the patient, how to recognise and manage signs of severity, complications and side-effects;
- depending on the type of home care, the cost, and conditions for reimbursement by national health insurance.

This information should be tailored to the patient and given as and when the patient is ready for it. A summary document or a recording of the visit should complete the oral information and subsequently be discussed with the GP. The patient is advised to come with a relative or a member of the household (if they do not live on their own) who can describe the patient's relationship with their entourage and their likes and dislikes.

[2] See circular DH/EO2/2000/295 of 30 May 2000.

When a patient wishes to be treated at home against the advice of the care team, the reasons should be discussed with them. In particular, the safety and social aspects of part-time hospitalisation should be discussed in relation to the treatment plan as a whole. This allows the doctor to explain their position. The doctor should always remain the sole judge of the level of responsibility he or she wants to commit to. Any refusal to allow chemotherapy at home should be documented, with reasons, in the medical record.

Conversely, the patient may feel safer in hospital, they may prefer not to think of their home as a place where they receive treatment, or they may not want to burden members of the household. The patient's opinion should prevail and should be noted in their medical record.

- Patient's psychological state

The patient's psychological state is not a formal eligibility criterion but a key to identifying patients who need special care or consideration. The hospital care team should ensure that at-home chemotherapy is not likely to disturb the patient's state of mind, and should compare it with treatment in hospital which might prove more disturbing. If the patient has a psychological disorder, the cause should be sought and, if necessary, the patient should be referred to a specialist and/or should receive symptomatic treatment. A state of agitation or confusion, dementia or delirium, persistence of symptoms under treatment, or severe anxiety or depression are likely to preclude or delay chemotherapy being given at home.

Patients learn to cope with their disease and its treatment gradually. They should have access to psychological support and, if necessary, be assessed periodically. The assessment may be carried out by psychologists or psychiatrists trained in psycho-oncology. However, this assumes that the fee for the service will be reimbursed, particularly when the psychologist is an independent practitioner.

Self-scored anxiety and depression questionnaires such as the Hospital Anxiety and Depression Scale (HADS) could be useful in helping to monitor the patient's psychological state and as an aid during consultations. Other scales tend to be research tools or for specialist use. There was no consensus within the working group on the use of self-scored quality of life questionnaires but the group emphasised that, if used, they should be accompanied by assessment protocols and/or specific validation of at-home care.

- Compliance with care

There are no rules for predicting compliance with treatment nor any validated risk factors. Each patient should be regarded as potentially non-compliant and compliance should not be assumed nor taken for granted. In view of the types of cancer chemotherapy concerned (oral or automated infusion), lack of compliance or risk of lack of compliance should not be reasons for refusing or suspending chemotherapy at home. The patient should be educated to reduce the lack of compliance by taking an active role in their treatment plan and, if necessary, a nurse should monitor the patient weekly to prevent lack of compliance.

- Patient's social support

Inadequate social support does not automatically contraindicate at-home chemotherapy. If a member of the care team notices inadequate support or if the patient complains of lack of support, a special consultation should be arranged, as well as intervention by a social worker, in order to find out how effective the patient's immediate social network is, what support is available, and whether someone who could help with care needs to be found, if the patient has not suggested someone. Discussion with the patient's GP, pharmacist, and home care nurse may clarify how good and how effective the social support is.

- Taking account of caregivers' preferences

If the patient feels they have no social support despite their social network, there may be dissent (actual or latent) between the patient and their caregivers. The care team should therefore ensure that the members of the patient's household and/or caregivers accept their roles. They should be guided into the role of helpers, particularly by being included in any educational measures. Their support and ability to adjust should be assessed at every consultation and nursing care session in order to bring to light any dissent and avoid their becoming exhausted. Relief could be offered by periodically admitting the patient to hospital. It may also be necessary to steer caregivers towards psychological support structures.

In the event of dissent or conflict between the patient and caregivers, a psychologist and social worker should intervene. Everyone involved in care should be informed but the confidentiality of discussions with the patient should not be breached.

Confirmation of a genuine problem, or its persistence despite psychological and/or social support, are serious obstacles to at-home chemotherapy. Decisions should then be taken on a case-by-case basis, with the reasons recorded in the patient's file. The patient and caregivers should be warned that decisions may be re-examined and changed at any time.

- ***Education of the patient and caregivers***

Whatever educational method is used, the skills a patient has to acquire will depend on the individual patient and on their treatment plan. Educational activities should be tailored to each patient and adjusted over time. The aim is to position the patient and caregivers as key partners in care.

The educational programme should be started during consultations, during meetings with a nurse and during the first chemotherapy cycle, and continued throughout chemotherapy. The patient is taught by the nurse or takes part in programmes offered by the hospital structure, care network or patient association (focus group, educational programme using written material, videos, etc.).

Before starting at-home care, a nurse should assess how well the patient has mastered the skills needed to implement the protocol safely. These include recognising and managing signs of severity, complications and side-effects, handling equipment, maintaining the venous access and recognising warning signs. Non-acquisition or partial acquisition of these skills is not in itself a reason for refusing at-home chemotherapy. Skills should routinely be reviewed in relation to protocol requirements, the presence and availability of the home care nurse, the possibility of involving the patient’s family or friends (except in actual care) and of providing further education in the hospital.

The working group recommended that, if the patient agrees, willing family members and friends should be asked to help in ensuring that the patient understands the care procedures and in assisting the patient with these procedures.

IV.2 Medical eligibility criteria

The working group felt that none of the following factors should exclude or restrict at-home chemotherapy: seriousness, severity or rate of progression of the disease, tumour type (solid tumour or malignant blood disorder), malnutrition or dehydration, patient age or performance status. However, some of these factors might be taken into account when suspending at-home chemotherapy, adjusting care, or deciding to transfer the patient to an appropriate

structure. The Karnofsky Performance Scale should be used to determine performance status (if possible, always scored by the same person), as it is already used by HAH structures to choose between periodic or continuous care.

If a state of agitation or deterioration in the patient's cognitive function is noted, the care team should seek a specialist opinion and postpone at-home chemotherapy. The cause of the symptoms should be sought and appropriate treatment given.

The anticipated onset of chemotherapy-induced side-effects such as nausea, vomiting, diarrhoea, mucitis, thrombocytopenia, anaemia or infection (list not exhaustive) is not specific to at-home care. Side-effects can be prevented or treated at home as they are during hospitalisation. They are not a criterion for giving up or rejecting at-home chemotherapy. The side effects noted during and after the first chemotherapy cycle in hospital are a good guide to the type and level of preventive measures and care the patient should be offered at home.

How a doctor takes each of these factors into account when deciding whether or not to offer at-home chemotherapy will vary with each individual.

IV.3 Eligibility criteria: Level of care and restrictions on daily life

The level of care required and the restrictions on the patient's daily life are key factors in the decision to offer at-home care. The first estimate of the level of care should be made by the hospital care team.

Care within a HAH structure: The supplement to the 30 May 2000 circular specified the level of care that justifies cancer chemotherapy within an HAH structure: care exceeding 1 hour and/or need for rehydration and/or need for supervision by a doctor or nurse for at least 24 hours. However, these criteria do not justify routine use of an HAH structure. The factors that call for HAH care are complexity of care, need for continuity and monitoring of care, and especially need for a range of care and staff (medical and paramedical personnel and social workers). In an HAH structure, members of staff should be available around the clock.

Care within a cancer care network: This depends on the network's capacity to offer and implement global multi-professional care that meets the patient's needs and care requirements.

The criterion for admission to such management of care is acceptance by the HAH or network coordinating doctor in the light of a detailed treatment plan and in agreement with the GP.

The main factors in a nurse's decision to accept or refuse to care for the patient at home, in terms of the current nomenclature, are the anticipated duration of care, his/her availability and the need to be present during infusion. However, these factors cannot predict whether the nurse will refuse or be able and willing to care for the patient at home or to take on all or part of the role of coordinating care around the patient.

Formal estimates should be obtained for:

- anticipated care requirements including at least the type and duration of care, the number of sessions and visits, and the duration of supervision by a doctor and nurse. This estimate should be produced by a hospital nurse in cooperation with the home care nurse and the patient's GP;
- home-help requirements as given by scales and checklists measuring handicap, incapacity and/or dependence. This estimate should be produced by the hospital social

worker with a nurse from the department where chemotherapy is prescribed, the allocated home social worker and the home care nurse.

All this information should be included in the nursing care record left at the patient's home for consultation by those involved, particularly social workers (shared record).

IV.4 Socioeconomic and environmental selection criteria

The patient selection process should include a review of the technical, practical, personal and socioeconomic aspects of at-home care, and identification of existing aid structures. This review requires input from both nursing and social work personnel, in cooperation with the GP and the structure's coordinating doctor.

The home care nurse and the hospital social worker can obtain much information from the patient, the person accompanying them, or the GP. However, technical and practical matters need to be assessed by an on-site visit. The working group recommended that the nurse and, if necessary, the social worker in charge of the case, visit the patient's home before agreeing to care at home. However, this assumes that the fee for the service will be reimbursed, especially when independent practitioners are involved.

When examining access to care, the home care nurse should ensure (if necessary by asking the coordinator of the care structure) that:
- the patient's GP, or failing them, a replacement GP nominated by the patient, agrees to care for the patient under the conditions required (particularly in terms of availability and transmission of information);
- medicines can be supplied by the local pharmacist, medical tests by a medical analysis laboratory and arrangements made for medical equipment by the local pharmacist or a service provider, under conditions ensuring that chemotherapy can be administered properly;
- an effective warning and emergency procedure can be arranged (including weekends and holidays) that takes into account the geographical location of the patient's home and the availability of those involved (nurse, GP, emergency services).

The aim of the safety review is to determine whether the home environment is suited to at-home chemotherapy. If drugs are to be prepared in the home, the nurse should take steps to check that:
- medicines can be handled in complete safety (a separate quiet room, with tightly-closing windows, protected from draughts, easy to clean and disinfect, with a smooth, non-absorbent and washable surface. There should be a refrigerator and easily-accessible storage space for products. All equipment needed should be present, as well as products needed to ensure the safety of individuals and for preparation, etc.);
- the patient has water, electricity, and a working telephone line (landline or mobile);
- there is enough space for any technical equipment;
- hygiene criteria are met (cleanliness, fittings and/or preparation of the home to avoid contact with animals or cut flowers (measures to prevent infection)).

A social worker should intervene if warning signs such as the following are detected in hospital:
- the patient is isolated (no social contacts, family, friends, neighbours, etc.);
- the patient is dependent;
- the patient has to look after other people;
- the patient's family or close friends are vulnerable;

- the patient reports practical, financial or administrative problems, particularly related to their social security cover and financial resources to cover the chemotherapy.

In practice, the social worker's remit is not limited to the first phase of reviewing the patient's eligibility for chemotherapy at home.

- Social workers may be asked by the nurse to assess the patient with regard to the points listed above at a later date, as part of the nursing care service.
- Longer observation by social workers may be requested to see if resources meet needs and if there are any malfunctions in the implementation of aid that might impact on keeping the patient at home.

V. Criteria for at-home chemotherapy and post-treatment monitoring

A criterion for at-home chemotherapy is access to coordinated care. This includes continuity of care and availability of permanent around-the-clock care (including Sundays and holidays). Care depends on sharing and circulating information.

Post-treatment monitoring should be covered by a quality improvement programme run by the hospital structure and/or care structures (HAH and care networks).

V.1 Continuity of care

- ***Patient discharge and care at home***

Continuity of care will be effective if the hospital care team and those involved in home care can work together and exchange information. This is particularly important in an emergency. A contact doctor should be nominated within the hospital department prescribing chemotherapy (this may be the prescribing doctor) or an interface team should be formed within the hospital. This doctor or team will be the contact for the GP, patient and at-home care coordinator (care structure’s coordinating doctor or the GP may take on this role).

In addition, the patient should be asked early on to provide details of a GP and a nurse who could contribute to their care at home and to invite them to a meeting, with the other individuals involved, if possible. However, this assumes that the fee for the service will be reimbursed, particularly where independent practitioners are involved.

If necessary, the hospital team should provide the GP and nurse with specific information on the anticancer drug and the expected course of at-home chemotherapy. This applies even though the care structure may have provided training for independent practitioners, the GP may have received training in at-home chemotherapy (e.g. continuing medical education), and regardless of the home care nurse’s qualifications.

The working group considered four types of document to be essential to continuity of care: the written treatment plan, prescriptions, a protocol summary and a sheet describing the procedure and giving information about cancer chemotherapy. These documents must be available to all involved when the patient is discharged.

- ***Modifying or suspending care***

In an emergency (as set out in the emergency procedure), the patient's safety and smooth transfer require that the department or, failing this, the hospital where at-home chemotherapy was prescribed, undertake to readmit the patient immediately. This assumes that the patient's record is readily available to the department admitting the patient.

Care requirements and the patient's needs may increase or decrease, requiring a change of care structure. The patient may prefer a simpler method of care, or at-home care may no longer be justified. The working group recommended that the treatment plan should anticipate such changes and describe their assessment and any procedures for changing or combining methods of care. HAH structures and care networks should take over care under the best possible conditions.

V.2 Permanent availability of care

Because the patient needs around the clock access to care, there should be a written record of the undertaking, role and responsibilities of those involved (professional or informal caregivers). This formal record should establish or restate the rules for working together on a daily basis and in an emergency (in particular, attendance, working together and delegation, on-call times).

The written emergency and warning procedure should include details of all those involved, warning indicators for when to call them out, and the measures and actions to be taken, particularly if an individual is not available.

A copy of this procedure should be available at the patient's home. It should be agreed, understood and signed by all before care begins (in particular, by the GP, nurse, coordinating doctor, the structure's nursing manager, emergency doctor/emergency centre, the contact doctor/hospital's prescribing doctor, and also by the patient (and the patient's caregivers), pharmacist, psychologist, social worker, care auxiliary and anyone else involved in care). It should be subject to specific quality control and a quality assurance procedure.

In practice, the medical care coordinator should establish the monitoring procedures on the basis of the drugs prescribed, the protocol summary and the cancer chemotherapy procedure and information sheet, in cooperation with the doctor prescribing chemotherapy. These procedures should be standard for each type of treatment within departments of a hospital structure, within a network and at regional level.

Side-effects and complications should be monitored jointly by:
- the patient or their caregivers, using the educational information and instructions provided;
- the nurse, during infusion sessions and clinical monitoring and preventive sessions;
- the GP, when called out by the patient or in accordance with a monitoring protocol established beforehand with the doctor prescribing chemotherapy.

Because of the treatment conditions and the properties of the drugs used, the working group stressed that all unanticipated, rare or life-threatening adverse events should be notified to the pharmacovigilance centre.

V.3 Sharing and circulation of information

There should be a single, common shared record that may be consulted by all caregivers. The working group felt that a paper record is best in view of the current problems with introducing electronic records. However, an electronic record should be developed.

The shared record should be left at the patient's home and be available to other caregivers. The patient should produce it at every visit for an update. It should be modelled on the nursing care record (i.e. include it or match it). There should be a section for use by other caregivers and, at the least, by the GP (notably for the go-ahead for chemotherapy). This record should be standard throughout France.

The record should be kept and completed by the nurse in their capacity as coordinator of paramedical personnel, and by the GP. It should include a section for patient identification and social and administrative data (particularly whom to contact, names and details of the caregivers and details of what to do in an emergency), and a section for the care plan, notably factors relating to at-home chemotherapy and post-treatment monitoring.

V.4 Chemotherapy monitoring

- ***GP's go-ahead***

On the day of the chemotherapy session, or the day before, the GP should visit the patient at home or examine them in the surgery, to give their approval for chemotherapy to begin. This approval should be recorded in the shared record and sent (by phone or fax) to the home care nurse if they are not present. The go-ahead is given after consultation with the contact doctor/chemotherapy prescriber, and should be based on the protocol produced by the doctor prescribing chemotherapy, taking particular account of:

- how the previous cycle was tolerated;
- the patient's clinical state (vital signs);
- whether laboratory test results meet the criteria in the protocol summary. These values and thresholds vary according to the protocol. In particular, they concern:
  - haematology (polymorphonuclear neutrophils, platelets),
  - renal function (blood creatinine),
  - liver function (blood bilirubin, transaminases).

- ***Complications related to use of the central venous route***

Complications related to the central venous route are monitored by:

- the nurse during infusion or monitoring sessions,
- the patient (or their caregivers) based on the educational information and instructions, including those in the implanted device brochure provided.

According to the working group, the complications that may occur at home include:

- suspected infection at the implantation site
- extravasation
- obstruction of the catheter
- venous thrombosis along the catheter tract
- ulceration or skin necrosis
- catheter rupture or migration
- acute respiratory distress.

If there are signs suggesting complications, the nurse should:
- first of all, if necessary, take the emergency measures specified in the emergency procedure and the cancer chemotherapy procedure and information sheet ;
- warn the GP or, failing this, the medical care coordinator and, if necessary, the contact doctor/cancer chemotherapy prescriber.

The GP (or doctor contacted) should assess the urgency of the situation and decide whether diagnosis and treatment are possible at home or whether the patient must be admitted to hospital. They should obtain a specialist opinion from the medical care coordinator and, if necessary, from the contact doctor/cancer chemotherapy prescriber.

The working group felt that if infection of the venous access is suspected, the patient should not necessarily be systematically and immediately admitted to hospital. The patient should only be admitted if the clinical situation is serious, in particular when clinical signs suggest deep infection or in the event of septic shock (in the absence of other signs of infection) or septic thrombophlebitis.

Instead, a specialist opinion may be sought and systemic antibiotics and/or antifungal agents may be prescribed while the results of microbiology tests are awaited. The patient should be monitored closely. This procedure should either be specified in the protocol summary or implemented using an advance prescription in the patient's name. It should be the subject of prior agreement between the co-ordinating doctor and the doctor prescribing chemotherapy. The decision should be reviewed as the clinical situation progresses and with due regard to the efficacy of treatment after 48 hours and microbiological test results.

Reflux of blood should be looked for before each infusion. If absent, a radiographic exploration should routinely be done with opacification of the catheter. Manoeuvres to remove an obstruction under pressure and the use of a low-volume syringe (1 or 2ml) are contraindicated.

- ***Monitoring criteria: Treatment and its side-effects***

The working group identified three main types of common complications (excluding metabolic disorders) that might require hospitalisation. These are infection, bleeding and anaemia. However, they saw no benefit in routine blood tests between treatment cycles unless specifically requested by the doctor prescribing chemotherapy, for instance when the treatment might cause aplasia or when there are signs or symptoms suggesting neutropenia, thrombocytopenia or anaemia.

- *Risk of (systemic) infection*

The warning signs of an infection that call for diagnosis and treatment are:
- fever or hyperthermia, defined as a single corrected axillary temperature reading over 38.3 °C (in practice, 38.5 °C) or 2 readings above 38 °C over 12 hours;
- shivering, circulatory failure.

However, the working group noted that a patient with no fever, but with signs and symptoms compatible with infection, should be regarded as being at risk of infection. For example, this would apply in the case of neutropenic patients with no initial fever who are infected by an aerobic organism such as *Clostridium septicum.*

In cases of febrile neutropenia (threshold values: $< 500/mm^3$ or $< 1\,000/mm^3$ with an anticipated fall of $< 500/mm^3$), a subgroup of patients with a low risk of serious complications can be defined with a good positive predictive value, by using validated prediction rules such

as the Talcott or MASCC criteria (level of evidence 2), in addition to the criterion of anticipated duration of neutropenia (< or ≥ 7 days).

The working group felt that, if a patient has a fever after cancer chemotherapy, they may continue to be cared for at home, after a medical examination excluding signs of severity or circulatory failure and provided that the risk of serious complications is low. The criteria for continuing home care and the details of test criteria (including CBC), treatment and monitoring should be approved beforehand by the doctor prescribing chemotherapy and written down in the protocol summary, and should be the subject of an advance prescription in the patient's name for the attention of a health professional.

Alternatively, onset of fever after chemotherapy may require an out-patient consultation for observation and tests (microbiology with blood culture and urine microscopy and culture, lab tests and chest X-ray). Depending on clinical progress and test results, the patient will either be admitted to hospital or sent home with appropriate antibiotic or antifungal therapy.

- Risk of bleeding

If thrombocytopenia is a risk, emergency admission to hospital should be decided on a case-by-case basis, as the threshold for prophylactic platelet transfusion varies according to diagnosis, the patient's clinical state and treatment (the value below is only a guide). Platelet transfusion should be given (and, if necessary, the patient hospitalised) if signs of bleeding are observed (e.g. bleeding gums, haemorrhage of the back of the eye, haematuria, petechiae). If these signs are absent, platelet transfusion should be given as soon as the threshold of 20 G/l is reached (level of evidence 1 for acute leukaemia and 4 for solid tumours, agreement among professionals).

- Risk of anaemia

According to French Health Products Safety Agency (AFSSAPS) guidelines, symptomatic anaemia is an indication for red blood cell transfusion. If aplasia is induced by chemotherapy, account should be taken of drug kinetics and the expected date of recovery from aplasia which should be specified in the protocol summary. As a guide, the infusion threshold is 8 g/dl if spontaneous correction of anaemia in the short-term is unlikely. The threshold may be higher, up to 10 g/dl if poor tolerance persists, particularly in elderly subjects or patients with cardiovascular disease.

- ***Other criteria for suspending or modifying chemotherapy at home***

Other criteria for suspending or modifying care at home identified by the working group were:
- if the chosen cancer chemotherapy protocol cannot be given at home (care should be taken with regard to product traceability and total dose administered to the patient);
- cancer chemotherapy finishes;
- the safety of the technical conditions has been compromised;
- the patient is dissatisfied or asks to suspend or modify care at home. This assumes that the patient has been asked regularly about quality of life;
- psychosocial conditions deteriorate (change in family members or caregivers; possible temporary interruption of treatment);
- the GP or the nurse refuses to continue to be responsible for the care.

VI. Conclusion and proposed future action

In conclusion, the working group emphasised that each of the criteria described above should not be considered in isolation but in relation to all the therapeutic, medical, psychological, social, environmental and administrative criteria that make up the treatment plan, which was designed to be consistent with the patient's life plan and preferences. The decision to give cancer chemotherapy at home if any of the criteria are not satisfied is left to the doctor to judge, in accordance with the responsibility they are prepared to accept on a case-by-case basis.

Annex 1 – Participants

Learned societies consulted

Association générale des infirmiers généraux
Centre de documentation et de recherche en médecine générale
Fédération des centres de lutte contre le cancer
Fédération nationale des établissements d'hospitalisation à domicile
Fédération nationale des infirmiers
Fédération française des oncologues médicaux
Ligue nationale de lutte contre le cancer
Société française de cancérologie privée
Société française du cancer
Société française d'hématologie
Société française de médecine générale
Société française de pharmacie clinique et de recherche
Société française de psychooncologie

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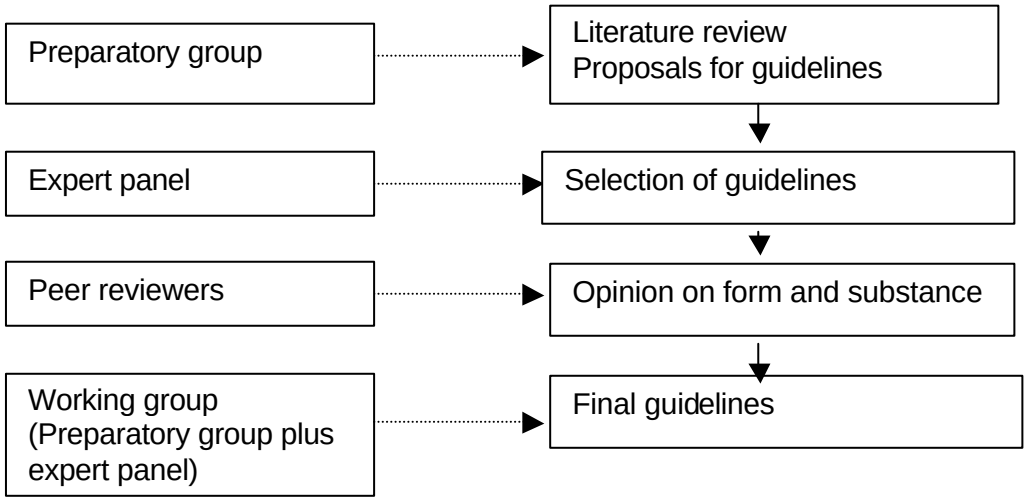
Annex 2 – Assessment method

The basis for all the guidelines was agreement among professionals using a formal consensus method derived from the nominal group technique adapted by RAND/UCLA. The technique used is illustrated in the diagram below (see also Annex 1 for participants).



Preparatory group. The ANAES project manager formed a group of professionals from a number of disciplines, working in public or private practice, from all over the country. Working in tight relation with the group and under the supervision of the chair of the group, he identified, selected, and analysed relevant studies (from a literature search performed by the ANAES Documentation Department – see below) and wrote a critical review. This review was then used by the group to propose draft guidelines reflecting all views (even contradictory views) within the group.

Expert panel. Expert panel members were appointed according to the same criteria as above. However, special attention was given to the inclusion of experts for whom at-home chemotherapy was a routine practice. The experts scored the draft guidelines (from 1 to 9) on the basis of evidence levels given in the report and of personal experience. They were first consulted by post, then convened to a discussion meeting following which they could modify their scores. Median scores and ranges were calculated. The final selection of guidelines was based on final score (integrating evidence level and agreement among members (this could be a high or a low level agreement)).

External validation (Peer reviewers). Peer reviewers were appointed as above. They were consulted by post, primarily with regard to the readability and applicability of the selected guidelines. The ANAES project manager summarized their comments and submitted them to the working group who took the final decisions on guideline selection and wording. Peer reviewers were invited to sign the final document.

Internal validation (Evaluation Section of the ANAES Scientific Council). Two members of the Council acted as referees. Together with the ANAES project manager,

they reported to the full Council. The working group finalized the guidelines with due regard to the Council's suggestions.

- ***Literature search and analysis (general procedure)***

The scope of the literature search was defined by the steering committee and the project manager. The search was carried out by the ANAES Documentation Department and focused on searching:

- medical and scientific databases over an appropriate period, with special emphasis on retrieving clinical practice guidelines, consensus conferences, articles on medical decision-making, systematic reviews, meta-analyses and other assessments already published nationally or internationally (articles in French or English)
- specific and/or financial/economic databases, if necessary
- all relevant websites (government agencies, professional societies, etc.)
- the grey literature (documents not identified through the usual information distribution circuits)
- legislative and regulatory texts

Further references were obtained from citations in the articles retrieved above and from working group members' and peer reviewers' own reference sources. The search was updated until the project was completed.

The articles selected were analysed according to the principles of a critical appraisal of the literature, using a checklist, to allocate a level of scientific evidence to each study. Whenever possible, the working group based its guidelines on this review of the literature. Guidelines were graded from A to C as shown in Table 1 depending on the level of the evidence of the supporting studies. If no grading is given, they are based on agreement among professionals.

Table 1. Grading of guidelines

Level of published scientific evidence	Grade
Level 1 Randomised controlled trials of high power Meta-analyses of randomised controlled trials Decision analyses based on properly conducted studies	**A:** Established scientific evidence
Level 2 Randomised controlled trials of low power Properly conducted non-randomised controlled trials Cohort studies	**B:** Presumption of scientific foundation
Level 3 Case-control studies	**C:** Low level of evidence
Level 4 Comparative studies with major bias Retrospective studies Case series	